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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,171	11/01/2006	Tacko Iino	47234-5002	1995
55694 7590 06/22/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 06/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,171	Applicant(s) IINO ET AL.	
	Examiner Michael C. Henry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/16/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-36 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 8, 11, 12, 14-18, 20, 23, 24, 25-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases “fatigue is prevented and improved”, “for prevention and improvement of fatigue” and “for preventing and improving fatigue” in claims 2-6, 8, 11, 12, 14-18, 20, 23, 24 render the claims indefinite. More specifically, it is unclear how fatigue can be prevented and improved simultaneously in order to practice the claimed invention since the conjunction “and” implies that fatigue is prevented and improved simultaneously, not in the alternatively.

Furthermore, it is unclear how fatigue can be improved as opposed to being treated.

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Claims 25-36 provide for “the use of proanthocyanidin ” but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 19, 21, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (US 6,372,266).

In claim 1, applicant claims an agent for improving physiological motor functions which is characterized in containing proanthocyanidin as an effective ingredient. Suzuki et al. disclose

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applicant's agent which is characterized in containing proanthocyanidin (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for improving physiological motor functions, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Suzuki et al.'s agent is the same as applicant's and thus should inherently have the same effect of improving physiological motor functions. Claim 2 is drawn to the agent for improving physiological motor functions according to claim 1, wherein fatigue is prevented and improved. Suzuki et al. disclose applicant's agent which is characterized in containing proanthocyanidin (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for improving physiological motor functions, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Suzuki et al.'s agent is the same as applicant's and thus should inherently have the same effect of improving physiological motor functions wherein fatigue is prevented and improved as recited in the claim. Claim 3 is drawn to the agent for improving physiological motor functions according claim 1, wherein muscular fatigue is prevented and improved. Suzuki et al. disclose applicant's agent which is characterized in containing proanthocyanidin (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for improving physiological motor functions, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that Suzuki et al.'s agent is the same as applicant's and thus should inherently have the same effect of improving physiological motor

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functions wherein muscular fatigue is prevented and improved as recited in the claim. Claim 4 is drawn to a health food for prevention and improvement of fatigue which is characterized in containing proanthocyanidin as an effective ingredient. Suzuki et al. disclose applicant's health food which is characterized in containing proanthocyanidin (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for prevention and improvement of fatigue, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claims 5-8 which are drawn to said health food which includes solid food, beverage and tablets are also anticipated by Suzuki et al. since Suzuki et al.'s health food also is in the form of a solid food, beverage and tablet (see abstract and col. 2, lines 1-11). Claim 9 is drawn to the agent for improving physiological motor functions according to claim 1, wherein proanthocyanidin is an extract derived from pine bark. Suzuki et al. disclose applicant's agent which is characterized in containing proanthocyanidin and which is an extract derived from pine bark (see abstract and col. 2, lines 1-11). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for improving physiological motor functions, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 10 is drawn to the agent for improving physiological motor functions according to claim 1, wherein proanthocyanidin is an oligomeric proanthocyanidin. Suzuki et al. disclose applicant's agent which is characterized in containing proanthocyanidin wherein the proanthocyanidin is an oligomeric proanthocyanidin (see abstract and fig.1). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for

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improving physiological motor functions, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim 11 is drawn to the health food for prevention and improvement of fatigue according to claim 4, wherein proanthocyanidin is an extract derived from pine bark. Suzuki et al. disclose applicant's health food which is characterized in containing proanthocyanidin and wherein proanthocyanidin is an extract derived from pine bark (see abstract and col. 2, lines 1-11). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for prevention and improvement of fatigue, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim 12 is drawn to the health food for prevention and improving fatigue according to claim 4, wherein proanthocyanidin is an oligomeric proanthocyanidin. Suzuki et al. disclose applicant's agent which is characterized in containing proanthocyanidin wherein the proanthocyanidin is an oligomeric proanthocyanidin (see abstract and fig.1). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for prevention and improvement of fatigue, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. In claim 13, applicant claims a method for improving physiological motor functions, characterized in that proanthocyanidin is administered to human being. Suzuki et al. disclose applicant's method for improving physiological motor functions (i.e., treating dysmenorrhea which is the occurrence of painful cramps (which is are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin is administered to a human (see abstract). Claim 19 is drawn to method for improving physiological motor functions according

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claim 13, wherein there is used a form of tablet, pill, capsule, granule, powder, diluted powder or liquid. Suzuki et al. disclose applicant's method for improving physiological motor functions (i.e., treating dysmenorrhea which is the occurrence of painful cramps (which is are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin in tablet form is administered to a human (see abstract). In claim 21, applicant claims the method for improving physiological motor functions according to claim 13, wherein proanthocyanidin is an extract derived from pine bark. Suzuki et al. disclose applicant's method for improving physiological motor functions (i.e., treating dysmenorrhea which is the occurrence of painful cramps (which is are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin, which is an extract derived from pine bark, is administered to a human (see abstract). In claim 22, applicant claims "the method for improving physiological motor functions according to claim 13, wherein proanthocyanidin is an oligomeric proanthocyanidin. Suzuki et al. disclose applicant's method for improving physiological motor functions (i.e., treating dysmenorrhea which is the occurrence of painful cramps (which is are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin, which is an oligomeric proanthocyanidin, is administered to a human (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-18, 20, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 6,372,266).

In claim 13, applicant claims a method for improving physiological motor functions, characterized in that proanthocyanidin is administered to human being. Claims 14-15 are drawn to said method wherein fatigue or muscular fatigue is prevented and improved. Claim 16 is drawn to a method for preventing and improving fatigue by characterized in that a health food containing proanthocyanidin as an effective ingredient is administered to human being. Claims 17-18, 20, 23, 24 are drawn to said method wherein the health food is in specific forms including solid food, beverage, tablet and wherein the proanthocyanidin is an extract derived from pine bark or is an oligomeric proanthocyanidin.

Suzuki et al. disclose that a composition comprising a pine bark extract and containing proanthocyanidins as an effective component thereof can be administered to a humans to treat leg cramps (i.e., sudden, involuntary, spasmodic muscular contraction causing severe pain) and chronic fatigue syndrome (see col. 2, line 20 to col. 3, line 8). Furthermore, Suzuki et al. disclose that the composition is widely used as a nutritional supplement foods see col. 2, lines 20-26). Furthermore, pine bark extract and containing proanthocyanidins can be in the form of tablets, liquid and powdery preparations.

The difference between applicant's claimed method and the method of Suzuki et al. is that Suzuki et al. do not exemplify the treatment or improvement of fatigue by administering the composition to said human. However, Suzuki et al. disclose that fatigue can be treated or improved by administering composition containing proanthocyanidin to a human being.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to improve or treat fatigue and physiological motor functions by administering Suzuki et al.'s composition containing proanthocyanidin to a human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat leg cramps (physiological motor functions) and chronic fatigue syndrome.

One having ordinary skill in the art would have been motivated, to improve or treat fatigue and physiological motor functions by administering Suzuki et al.'s composition containing proanthocyanidin to a human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat leg cramps (physiological motor functions) and chronic fatigue syndrome.

Conclusion

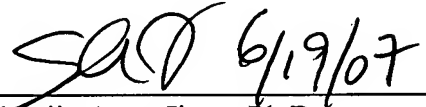
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

 6/19/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 18, 2007.